GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2876
ANSWERED ON:05.12.2007
IMPROVEMENT IN QUALITY OF MEDICINES
Chowdhury Shri Adhir Ranjan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the data by which the Government can improve the quality of medicines;

(b) the difference in various changes of GMP guidelines of WHO and Schedule M notified by the Government of India;

(c) whether uniform guidelines for inspection have been notified by the Government for the changes required under schedule M and GMP;

(d) if so, the details thereof; and

(e) if not, the reasons therefore?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT.PANABAKA LAKSHMI)
(a) The Government proposes to improve the quality of medicines by introducing stringent conditions for manufacture and quality control known as Good Manufacturing Practics (GMPs) notified under Schedule M of the Drugs & Cosmetics Rules. The main objective of this requirement is to prevent cross contamination and ensure consistency.
(b) The Government has not notified the differences that are observed between Schedule M and WHO GMP requirements.
(c) & (d) No uniform guidelines for inspections have been notified. Inspections of manufacturing units have to be carried out for compliance of GMP requirements as specified under Schedule M which are statutory requirements under the Drug and Cosmetics Rules.
(e) Inspections of manufacturing units are carried out as per the Schedule M (GMP) of the Drugs and Cosmetics Rules which are sufficiently adequate for ensuring proper quality of drug manufacture.